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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,434	07/18/2002	Michael B Thornton	PI-0137 USN	3714
22428	7590	06/03/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/069,434

Applicant(s)

THORNTON ET AL.

Examiner

Tekchand Saidha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-2, 16-18 & 45, drawn to polypeptide of SEQ ID NO : 1 [human lyase (HLYA-1)] and composition thereof.

Group 2, claims 3-9, 11-12 & 48, drawn to DNA of SEQ ID NO : 4 encoding HLYA-1, vector, host cell and a recombinant method of making the polypeptide.

Group 3, claim(s) 1-2, 16-18 & 46, drawn to polypeptide of SEQ ID NO : 2 [human lyase (HLYA-2)] and composition thereof.

Group 4, claims 3-9, 11-12 & 49, drawn to DNA of SEQ ID NO : 5 encoding HLYA-2, vector, host cell and a recombinant method of making the polypeptide.

Group 5, claim(s) 1-2, 16-18 & 47, drawn to polypeptide of SEQ ID NO : 3 [human lyase (HLYA-3)] and composition thereof.

Group 6, claim(s) 3-9, 11-12 & 50, drawn to DNA of SEQ ID NO : 6, vector, host cell and a recombinant method of making the polypeptide.

Group 7, claim(s) 10 & 29-44, drawn to antibody against polypeptide of SEQ ID NO : 1 and method of use.

Group 8, claim(s) 10 & 29-44, drawn to antibody against polypeptide of SEQ ID NO : 2 and its use.

Group 9, claim(s) 10 & 29-44, drawn to antibody against polypeptide of SEQ ID NO : 3.

Group 10, claim(s) 13-15, drawn to a method of detection using the polynucleotide of SEQ ID NO : 4.

Group 11, claim(s) 13-15, drawn to a method of detection using the polynucleotide of SEQ ID NO : 5.

Group 12, claim(s) 13-15, drawn to a method of detection using the polynucleotide of SEQ ID NO : 6.

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Group 13, claim(s) 19-24 & 26, drawn to method of screening an agonist or antagonist of polypeptide of SEQ ID NO : 1 and methods of use.

Group 14, claim(s) 19-24 & 26, drawn to method of screening an agonist or antagonist of polypeptide of SEQ ID NO : 2 and methods of use.

Group 15, claim(s) 19-24 & 26, drawn to method of screening an agonist or antagonist of polypeptide of SEQ ID NO : 3 and methods of use.

Group 16, claim(s) 25, drawn to method of screening a compound that specifically binds to the polypeptide of SEQ ID NO : 1.

Group 17, claim(s) 25, drawn to method of screening a compound that specifically binds to the polypeptide of SEQ ID NO : 2.

Group 18, claim(s) 25, drawn to method of screening a compound that specifically binds to the polypeptide of SEQ ID NO : 3.

Group 19, claim(s) 27, drawn to method of screening a compound that alters expression of target polynucleotide of SEQ ID NO : 4.

Group 20, claim(s) 27, drawn to method of screening a compound that alters expression of target polynucleotide of SEQ ID NO : 5.

Group 21, claim(s) 27, drawn to method of screening a compound that alters expression of target polynucleotide of SEQ ID NO : 6.

Group 22, claim(s) 28, drawn to method of assessing toxicity using polynucleotide of SEQ ID NO : 4 or fragment thereof.

Group 23, claim(s) 28, drawn to method of assessing toxicity using polynucleotide of SEQ ID NO : 5 or fragment thereof.

Group 24, claim(s) 28, drawn to method of assessing toxicity using polynucleotide of SEQ ID NO : 6 or fragment thereof.

2. The inventions listed as Groups 1-24 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group 1 has the special technical feature of the nucleotide sequence of SEQ ID NO : 4, host cell

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and a method of making the polypeptide, which Groups 2-24 do not share. For the same reason, each of the Groups 2-6 has the special technical feature of the distinct nucleotide sequence of SEQ ID NOS : 5 or 6 or the encoded polypeptides of SEQ ID NOS : 2 or 3, respectively, host cell and a method of making the polypeptide, which Groups 1 & groups 7-24 do not share. Each of the Groups 7-9 have a special technical in a distinct antibody pertaining to each of the polypeptide sequences of SEQ ID NOS : 1-3, which Groups 1-6 & Groups 10-24 do not share. Each of the Groups 10-24, employ structurally distinct nucleotide sequences of SEQ ID NOS : 4-6 or the polypeptide sequences of SEQ ID NOS : 1-3 in distinct methods, however, in view of 37 CFR 1.475(b), when claims corresponding to different categories of inventions are present then only (3) applies and additional methods of use are deemed to lack unity. Thus the various groups discussed above show a lack of unity of invention.

Notice of Possible Rejoinder

The Examiner notes that if product claims in Group BLAH are found directed to an allowable product, then process claims in Group BLAH, which are directed to processes of making or using the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

3. "A telephone restriction requirement was not made in this application due to an explicit request by Incyte and their policy of not making elections in response to telephonic restriction requirements."

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

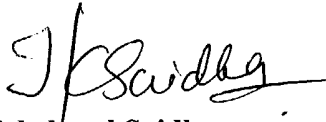
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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



Tekchand Saidha

Primary Examiner, Art Unit 1652

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May 31, 2004